

REMARKS

1. Applicants acknowledge with appreciation the indication of allowable subject matter of claim 6.
2. Claims 8 and 11 have been rejected under 35 USC § 102(b) as being anticipated by Schraner. Schraner discloses the results of an investigation of the effects of the complex drug Influenx and an *Echinacea angustifolia* extract 1) on immunoglobulin and antibody synthesis in chickens immunized with human serum albumin and 2) on IgG synthesis in immunodeficient chickens. The preparations were administered orally, however, there is no indication of what was present in the composition administered besides the active test components. It is well-established that, in order for a reference to be properly applied under § 102, that reference must meet each and every limitation of the claims to which it has been applied. It is respectfully urged that the Schraner reference falls short of that requirement. First, claim 8 as amended is a composition comprising an *Echinacea* preparation and poultry feed. Schraner is completely silent with respect to the components of the preparation administered to the chickens, therefore one cannot merely assume that it is administered with poultry feed. Second, the claimed composition is effective for enhancing an immune response to an anticoccidial

vaccine. Schraner investigated the response to the combination of an *Echinacea* extract and administration of human serum albumin with respect to immunoglobulin and antibody synthesis, but reported no results. Only the administration of the complex drug resulted in a rise in serum immunoglobulin concentration and an increase in antibody levels. For these reasons, it is believed that the reference has been improperly applied under § 102, and it is requested that the rejection be withdrawn.

3. Claim 8 has been rejected under 35 USC § 102(b) as being anticipated by Hockertz. The Hockertz reference contains one mention of "a pressed echinaceae-preparation" in the abstract. Again, the requirements for application of a reference under § 102 is pointed out, and it is urged that Hockertz does not meet those requirements. First, the claimed composition is comprised of an *Echinacea* preparation and poultry feed. Hockertz is completely silent with respect to a composition and does not mention poultry or poultry feed under any circumstances. Second, the abstract appears to relate to the immunomodulator Uro-Vaxom (FEC) and its application to mouse macrophages (a mammalian system) to test their secretory, immuno-regulatory and cytotoxic functions. "In comparison to a pressed echinaceae-preparation, FEC activated mouse macrophages secrete Interleukin-6 and tumor-

necrosis-factor and kill protozoa, fungi and bacteria, with higher efficiency." A preparation having such a result in mice clearly does not anticipate a composition "effective for enhancing an immune response to an anticoccidial vaccine" in poultry. For these reasons, it is believed that the reference has been improperly applied under § 102, and it is requested that the rejection be withdrawn.

4. Claims 8-9 and 11 have been rejected under 35 USC § 102(b) as being anticipated by Kutilek. Kutilek discloses a dietary supplement comprising "an effective mixture of herbal exrtracts and powders, vitamins, minerals, amino acids, and various excipients" consumable as a tablet, capsule or beverage to treat human or animal subjects for bacterial, fungal and viral infections or other opportunistic infections in immunocompromised or immunosuppressed subjects. Again, the requirements for application of a reference under § 102 is pointed out, and it is urged that Kutelik does not meet those requirements. Kutelik does not teach an *Echinacea* preparation in combination with poultry feed, as is recited by amended claim 8. Moreover, Kutelik teaches administration of the dietary supplement by tablet, capsule or beverage, which is inconsistent with the poultry feed component of the instantly claimed composition. For

this reason, it is believed that the reference has been improperly applied under § 102, and it is requested that the rejection be withdrawn.

5. Claims 8 and 10-11 have been rejected under 35 USC § 102(e) as being anticipated by Squires. Squires discloses a composition used for topical treatment of herpes virus and other microbial infections. The composition "is a phytochemical concentrate which is combined and simultaneously or concurrently applied with a surfactant and a carrier, solvent or diluent to provide a microbicide medicinal solution." Again, the requirements for application of a reference under § 102 are pointed out, and it is urged that Squires does not meet those requirements. First, Squires discloses a composition which is utilized topically and does not contain poultry feed. The carriers pointed to are not conventional poultry feeds. Moreover, upon consideration of other components of the medicinal solution, i.e. surfactants, the composition would not be expected to be ingestible. Second, the medicinal solution would not be effective for enhancing an immune response to an anticoccidial vaccine. It is clear that the phytochemical concentrate is the active ingredient which directly attacks the particular microbial objective. The immune response is not regarded as important to the treatment and a vaccine is

not even mentioned as a consideration in the objective of the treatment protocol. While it is recognized that inherency is an issue which must be considered, it is urged that a composition which is effective as a topical treatment, acts directly on an infectious agent and is not ingestible does not anticipate a composition which is administered internally and acts upon the infectious agent by enhancing the immune system's response to a vaccine. For these reasons, it is believed that the reference has been improperly applied under § 102, and it is requested that the rejection be withdrawn.

6. Claims 1-5 have been rejected under 35 USC § 103(a) as being unpatentable over Kutilek in view of Schraner and Davis.

Kutilek discloses a dietary supplement comprising "an effective mixture of herbal extracts and powders, vitamins, minerals, amino acids, and various excipients" consumable as a tablet, capsule or beverage to treat human or animal subjects for bacterial, fungal and viral infections or other opportunistic infections in immunocompromised or immunosuppressed subjects. It is alleged that Kutilek also provides "an additional anti-coccidial component and ingestible carrier, wherein Kutilek, III et al teach the combination of the anti-coccidial Echinacea composition in association with an additional anti-coccidial component..."

Applicants have been unable to locate such a teaching in the Kutilek disclosure. Moreover, coccidia has not been mentioned at all. Although Kutilek mentions poultry in passing, there are no teachings which would enable one to utilize the dietary composition as described in the instant invention or to motivate one to utilize a dietary composition as described in the instant invention. First, Kutilek teaches administration by tablet, capsule, powder or beverage. None of these means are equivalent to administration by mixing with poultry feed, nor do they suggest it. Second, the objective of the Kutilek invention is to alleviate adverse health conditions in immunosuppressed or immunocompromised patients, and all the examples are directed to administration to cancer patients who are undergoing either radiation or chemotherapy treatments. The instant invention, on the other hand, has the objective of alleviating a problem with resistance in avian coccidia populations to the current drugs utilized in the prophylactic treatment of entire flocks of poultry in conjunction with vaccination with anticoccidial vaccines. To apply a treatment for cancer patients to the treatment of poultry flocks for the enhancement of vaccinations against coccidiosis is a considerable stretch.

As pointed out by the Examiner, Kutilek "differs from the instantly claimed invention by failing the additional anti-

coccidial component to be a coccidial vaccine." As already pointed out, Kutilek does not point out any anti-coccidial component, much less vaccine. Schraner is relied upon to supply the missing component, however, it is well-established that, under § 103, there must be some motivation to combine references in order to properly apply those references in combination to rejected claims. It is urged that one of skill in the art would not be likely to utilize such a combination as relied upon as a suggestion to administer the claimed

Echinacea suppliment in combination with a vaccine due to any teachings from Schraner for the reasons discussed in paragraph

2. Schraner disclosed an investigation of the effects on immunoglobulin and antibody synthesis in chickens immunized with human serum albumin and on IgG synthesis in immunodefective chickens by the complex drug Influx and an *Echinacea angustifolia* extract. Human serum albumin may be an immunogen, however it is not a vaccine. At any rate, Schraner did not disclose any results related to the albumin/*Echinacea* extract combination. Only the administration of the complex drug resulted in a rise in serum immunoglobulin concentration and an increase in antibody levels. Relying on Schraner, one would not expect to successfully enhance immune response to vaccination by utilizing an *Echinacea* preparation.

Davis is additionally relied on because Davis teaches administering anti-coccidial inoculants in poultry feed. Various additional ingredients may also be included in the composition, such as carriers, amino acids, minerals and anti-coccidial drugs at subcurative levels.

According to the Examiner, "it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose; the idea of combining them flow logically from their having been individually taught in the prior art." First, it is unclear what two compositions have been combined, and second it is unclear what the third composition is. Second, the idea of combining them may flow logically, but only if the facts support it. It is submitted that, in this case, they don't. A summary of the relevant teachings of the three references is presented below:

	Immune Enhancement	Anti-Coccidial Vaccine	Poultry Feed
Kutilek	X	-	-
Schranner	-	-	-
Davis	-	X	X

Kutilek shows only immune enhancement, but exemplifies only in cancer patients or those who are immunocompromised or immunosuppressed; there is no mention of the use of anti-coccidial vaccines or poultry feed. On close examination of the reference, Schraner provides nothing of use to one of skill in the art relevant to the invention. No immune enhancement is shown (only the complex drug has a result), and no mention is made of the use of anticoccidial vaccines or of poultry feed. Davis shows anti-coccidial vaccines and poultry feed, but no immune enhancement. Davis suggests additionally utilizing anti-coccidial drugs in the anti-coccidiosis treatment, but as an active ingredient, not for immune enhancement. Eliminating Schraner as irrelevant for the reasons given above, Kutilek and Davis are left in combination, however, the logic for combining them does not flow since the two compositions were not used for the same purpose. The Kutilek composition was utilized to treat immunosuppressed or immunocompromised patients to bring their immune responses to something approaching normal, due to radiation or chemical treatments for cancer. Poultry was mentioned in a laundry list of all animals which might achieve beneficial results, but there is so little discussion of that aspect that there is nothing for one to rely on. The Davis composition, on the other hand, was utilized to vaccinate healthy

(not immunosuppressed or immunocompromised) poultry to prevent coccidial infection. These are two very different purposes, and it is urged that applicants' invention has provided a template for picking and choosing various parts of various publications to fit the elements of applicants' invention. There is no reason why one of skill in the art would have combined a treatment used for cancer patients with a vaccination method for prevention of coccidiosis in poultry to arrive at the instant invention. It is thus respectfully urged that there was no motivation to combine the three references, and it is requested that the rejection be withdrawn.

7. Claim 7 has been rejected under 35 USC § 103(a) as being unpatentable over Kutilek in view of Davis and Schraner and further in view of Squires. Claim 7 limits the *Echinacea* of the supplement composition to *Echinacea purpurea* (*E. purpurea*). None of Kutilek, Davis and Schraner disclose *E. purpurea*, and Squires is relied upon to fill that gap. For the reasons discussed above in paragraph 6, it is urged that the claim is neither suggested nor taught by the combination of references, because Squires does nothing to cure the deficiencies already discussed. Moreover, as discussed in paragraph 5, the *E. purpurea* composition disclosed by Squires is for topical application, and is most likely not

even ingestible at all. There is certainly no suggestion for ingesting it, and, since coccidiosis in an internal not an external infection, it is urged that the Squires reference actually teaches away from the instant invention of internal administration. In addition, Squires utilizes the composition as an active ingredient which directly attacks the infectious agent, not as one which enhances the immune response of the host to vaccination against that agent. For these reasons, it is respectfully urged that there is no motivation to combine these references, therefore a rejection under § 103(a) is not proper. It is therefore requested that the rejection be withdrawn

It is believed that in view of the above amendments and remarks, the instant application is now in condition for allowance. Accordingly, it is respectfully requested that the objection and rejections be withdrawn and the application be allowed to issue. If any issues remain to be discussed, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,

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* Janelle S. Graeter 2-5-03 *
* (Signature) (Date) *

Version with Markings to Show Changes Made

1. (Twice amended) A method for protecting poultry against coccidiosis, said method comprising inoculating chicks with an effective amount of an anticoccidial vaccine and providing a dietary regimen composition comprising an *Echinacea* supplement in an amount effective for enhancing an immune response to said vaccine and [an ingestible carrier] poultry feed.

8. (Amended) A dietary composition for poultry, said composition comprising an *Echinacea* preparation in an amount effective for enhancing an immune response to an anticoccidial vaccine and [an ingestible carrier] poultry feed.

Cancel claims 5 and 11.

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